Notice of Allowability	Application No.	Applicant(s)	
	09/863,125	LIGHT, ELIZABETH S.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *RCE filed 22 February 2006*.

2. ☒ The allowed claim(s) is/are *27,29 and 30*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

 * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

 Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance: Claims 27, 29 and 30 are allowable over the combined teachings of Vernole, (*Biotechniques*, Vol. 9, No. 2 (1990) pp. 200-204), Davison et al., *American Journal of Pathology*, Vol. 153, No. 5, November 1998, pp. 1401-1409), and US Patent 4,935,341 (Bargmann et al.), the closest prior art of record. Vernole teaches performing *in situ* hybridization reactions where hybridization products are detected via use of digoxigenin alkaline phosphatase-conjugated antibodies are employed. Rather than using bright field microscopy, Vernole teaches using phase contrast microscopy.

2. Davison et al., teaches performing *in situ* hybridization on tissue sections (page 1403, right column) that have undergone protease treatment. Davison et al., page 1406, right column, teaches explicitly of being able to detect hybridization products, including chromosomal rearrangements, via bright-field microscopy. While Davison et al., do teach of broadly applying their technology, they block repeated sequences such that one is only looking at that in the chromosome, including translocation events. In contrast, the claimed method requires one to be able to detect single copy genes in the nucleus and that there are to be "separate and distinct" signals in nucleus and cytoplasm, limitations not found in the prior art.

3. Bargmann et al., teach isolating and cloning nucleic acids that correspond to HER-2/neu. While Bargmann et al., do disclose detecting point mutations, such is achieved by cloning, transforming and analysis of the then amplified nucleic acid. Bargmann et al., effectively teaches away from doing their analysis via *in situ* hybridization.

4. For the above reasons, and in the absence of convincing evidence to the contrary, claims 27 and 29-30 are allowable over the combined teachings of Vernole, Davison et al., and Bargmann et al., the closest prior art of record.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
06 March 2006